amended; claims 11-15 have been newly added; and claim 2 has been cancelled. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with Markings to Show Changes Made**." Applicants respectfully submit that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

In the Office Action, claims 1-10 are rejected under the judicially created doctrine of obviousness–type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 5,661,123; claims 1-22 of U.S. Patent No. 6,200,950; and claims 1-20 of U.S. Patent No. 5,549,905. In response, Applicants are submitting herewith a Terminal Disclaimer. Applicants respectfully that the Terminal Disclaimer overcomes the double patenting rejection.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness–type double patenting as being unpatentable over claims 1-22 of co-pending U.S. Patent Application No. 09/759,037. In response, Applicants respectfully submit that upon Notice of Allowability of either one of the co-pending applications that a Terminal Disclaimer will be filed to address this rejection. Therefore, Applicants believe that they have been fully responsive to this provisional rejection.

In the Office Action, claims 4 and 6-9 are objected to under 37 C.F.R. § 1.75. The examiner alleges that claim 4 is substantially identical to claim 2 and that claims 6-9 are in improper form. As previously discussed, claim 2 has been cancelled and claims 6-9 have been amended. Therefore Applicants respectfully submit that the claimed invention fully complies with 37 C.R.F. § 1.75.

Accordingly, Applicants respectfully that this objection be withdrawn.

In the Office Action, claims 1-7, 9-10 are rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,504,072 ("*Schmidl*"). As previously discussed, the sole pending independent claims, namely claims 1, 4 and 10, have been amended. In view of the amendments and for the reasons set forth below, Applicants believe that this rejection has been overcome.

Independent claim 1 recites an enteral composition designed for metabolically stressed patients that includes a protein source with about 15% to about 18% of the energy of the composition; a carbohydrate source; and a lipid source including a mixture of medium and long chain triglycerides wherein the enteral composition has a caloric density of at least about 1.4 kcal/ml. Independent claim 4 recites an enteral composition for a metabolically stressed patient that includes about 15% to about 18% of the energy of the composition of partially hydrolysed whey protein; a carbohydrate source; and a lipid source including a mixture of medium and long chain triglycerides wherein the composition has an energy density of at least about 1.4 kcal/ml and a ratio on non-protein calories per gram of nitrogen of at least about 90:1. Independent claim 10 recites a method of providing nutrition to a metabolically stressed patient that includes administering to the patient a therapeutically effective amount of a composition. The composition includes a protein source including approximately 15% to about 18% of the energy composition; a carbohydrate source; and a lipid source including a mixture of medium and long chain tryglycerides wherein the enteral composition has a caloric density of at least about 1.4 kcal/ml.

The claimed invention provides a product that is specifically directed to meet nutritional needs of metabolically stressed patients without elevated protein levels or excess fluid. To this end, the claimed invention provides calorically dense nutritional support in the form of an enteral composition while at the same time providing a moderate non-protein calories per gram of nitrogen ("NPC/gN") ratio. As previously discussed, the enteral composition of the claimed invention includes, in part, a protein source that provide about 15% to about 18% of the total energy of the composition wherein the enteral composition has a caloric density of at least about 1.4 kcal/ml. For adults and older children (10 plus years or older), for example, the protein concentration is optimal for the moderate tissue repair needs of the targeted patient populations without imposing an undue nitrogen burden on renal function. See, specification, Page 4, lines 4-17.

In contrast, *Schmidl* fails to disclose or suggest a number of features of the claimed invention. Of course, an anticipation rejection requires that "there must be no difference between the claimed invention and a reference's disclosure as viewed by a person of ordinary skill in the filed of the invention." *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927

F.2d 1565 (Fed. Cir. 1991). Accordingly, "for a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990).

Indeed, *Schmidl* fails to disclose or suggest, for example, an enteral composition that has a caloric density of 1.4 kcal/mL as required by the claimed invention. This is a critical issue with respect to the patient population of Applicants' claimed invention. In contrast to the claimed invention, *Schmidl* states "the composition can also be in the form of a ready-to-use aqueous liquid which preferably has a caloric content of 1 kcal/mL." See, *Schmidl* column 7, lines 54-57.

If anything, *Schmidl* teaches away from the claimed invention. The mere fact that a composition has lipids, carbohydrates, and protein does not mean the composition has the same caloric density as another composition including lipids, carbohydrates, and proteins. Simply because a product has lipids, carbohydrates, and protein does not mean it has the same characteristics as another product having lipids, carbohydrates, and protein. There are millions of compositions including a lipid, a carbohydrate, and a protein that have different properties. Thus, clearly the anticipation rejection is improper in view of this fact alone.

Accordingly, Applicants respectfully request that the anticipation rejection be withdrawn.

In the Office Action, claims 1-8 and 9-10 are rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,221,668 ("*Henningfield*"). Applicants believe that *Henningfield*, like *Schmidl*, fail to disclose or suggest a number of features of the claimed invention.

For example, Applicants do not believe that *Henningfield* discloses or suggests an enteral composition for metabolically stressed patients that includes, in part, a protein source, such as partially hydrolysed whey proteins, that include about 15% to about 18% of the energy of the composition. As previously discussed, Applicants have found that the total amount of energy from about 15% to about 18%, such as 16%, provided by the protein source is optimal for moderate tissue repair needs of the targeted patient populations without imposing an undue nitrogen burden on renal function. Indeed, *Henningfield* discloses that about 20.5% of the

calories provided by proteins is preferred. One skilled in the art viewing same would clearly consider *Henningfield*, for this reason alone, to be deficient with respect to the specific compositional features of the claimed invention. Therefore, Applicants believe that *Henningfield* fails to anticipate the claimed invention.

Accordingly, Applicants request that this rejection be withdrawn.

In the Office Action, claims 1-10 are rejected under 35 U.S.C. § 102 as being anticipated by, or in the alternative, under 35 U.S.C. § 103 as obvious over U.S. Patent No. 5, 714,472 ("*Gray*"). Applicants believe that *Gray*, like *Henningfield* and/or *Schmidl*, fail to disclose or suggest a number of features of the claimed invention.

For example, Applicants do not believe that *Gray*, like *Henningfield*, discloses or suggests an enteral composition for metabolically stressed patients that includes, in part, a protein source, such as partially hydrolysed whey proteins, with about 15% to about 18% of the energy content of the composition. Indeed, the Examiner admits that *Gray* merely provides "about 22%" of the energy of the composition. See, Office Action, page 7. This is clearly not substantially the same as an enteral composition with a protein energy content of about 15% to about 18% as the Examiner would seem to suggest. Moreover, *Gray* discloses that the total non-protein calories per gram of nitrogen should be less than or equal to 70:1. This clearly contrasts Claim 4 which requires, in part, a ratio of non-protein calories per gram of nitrogen of at least about 90:1. Therefore, Applicants do not believe that *Gray* anticipates and/or renders obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claim 8 is rejected under 35 U.S.C. § 103 as being unpatentlable over *Schmidl* in view of *Gray*. As previously discussed, claim 8 has been amended to depend from independent claim 4 and therefore incorporates each and every feature of claim 4.

In contrast, *Schmidl* and/or *Gray*, even if combinable, fail to disclose or suggest a number of features of claim 8. In this regard, the Examiner admits that *Schmidl* fails to incorporate beta-carotene and L-cystine to their enteral formula. See, Office Action, page 9. The Examiner relies on the purported teachings of *Gray* to remedy this deficiency.

However, *Schmidl* is also clearly deficient with respect to an enteral composition that has a caloric density of at least about 1.4 kcal/ml as required by the claimed invention. In fact, the preferred caloric density of *Schmidl* is 1.0 kcal/ml. This effectively teaches away from claimed invention as previously discussed. Again, the Examiner appears to merely rely on *Gray* for its purported teachings regarding the beta-carotene feature of Claim 8. Therefore, Applicants do not believe that *Schmidl* and *Gray*, even if combinable, render obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-10 are rejected under 35 U.S.C. § 103 as being unpatentlable over U.S. Patent No. 5,166,189 ("*Trimbo*") in view of *Schmidl*, *Gray*, U.S. Patent No. 4,427,658 ("*Maubois*") and further in view of *Granger et al.* The Patent Office primarily relies on *Trimbo* and thus relies on the other cited references to remedy its deficiencies.

In contrast, the cited art fails to disclose or suggest a number of features of the claimed invention. For example, *Trimbo* is deficient with respect to a number of features of the claimed invention even as admitted by the Examiner. See, Office Action, page 10. For example, *Trimbo* is deficient with respect to an enteral composition suitable for metabolically stressed patients that includes, in part, a protein source providing about 15% to about 18% of the energy content wherein the composition has a caloric density of at least about 1.4 kcal/ml.

Indeed, *Trimbo* discloses that the composition contains no less than 18% of the calories as protein and an energy content of 1.2 kcal/ml. As previously discussed, the enteral composition includes a protein source that provides about 15% to about 18% of the total energy of the composition wherein the enteral composition has a caloric density of at least about 1.4 kcal/ml. For adults and older children (10 plus years or older), for example, the protein concentration is optimal for the moderate tissue repair needs of the targeted patient populations without imposing an undue nitrogen burden on renal function.

Further, the remaining references, even if combinable, cannot remedy the deficiencies of *Trimbo*. For example, nowhere do any of these references, alone or in combination, disclose or suggest the protein energy content and caloric density features of the claimed invention. As previously discussed, *Schmidl* effectively teaches away from the caloric density of the claimed

invention. Further, *Gray* discloses a protein source energy content that is clearly outside of the scope and content of the claimed invention as discussed above.

Contrary to the Patent Office's position, *Maubois* fails to disclose or suggest, for example, protein intake ranging from 7% to 25% of the total caloric intake. Examples 5 and 6 merely suggest that the protein intake can be 7% to 12% (Example 5) or 25% of the total caloric intake. This is clearly does not suggest the protein energy content of 15% to 18% as required by the claimed invention. Moreover, the Patent Office merely relies on *Granger* for its purported teaching relating to providing elemental protein to hypermetabolically stressed patients. Therefore, Applicants do not believe that one skilled in the art viewing the cited art, in any hypothetical combination, would be inclined to modify *Trimbo* to arrive at the claimed invention.

What the Patent Office clearly has done is to simply piece together the cited art by selectively picking and choosing teachings from disparate art in an attempt to explain what the claimed invention discloses. The Court of Appeals for the Federal Circuit has criticized this motivation to combine analysis as being "hindsight reconstructive" because the motivation to combine the references was first disclosed in the present invention. *In re O'Farrell*, 853 F.2d 894, 902-903 (Fed. Cir. 1988).

As previously discussed, *Trimbo* is clearly deficient with respect to a number of features of the claimed invention as even admitted by the Patent Office. Further, nowhere does any one or any hypothetical combination of the remaining references disclose or suggest, for example, an enteral composition that includes both a protein source that provides about 15% to about 18% of the energy of the composition wherein the composition has a caloric density of at least 1.4 kcal/ml. For example, *Schmidl* and *Gray* effectively teach away from a composition with such features as previously discussed. Further, *Maubois* is clearly deficient, for example, with respect to the protein energy content of the claimed invention. Indeed, *Maubois* fails to specifically address the U.S. RDA's nutritional needs of metabolically stressed patients as even admitted by the Examiner. Therefore, Applicants believe that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the present application and earnestly solicit allowance of same.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1 and 3-10 have been amended as follows:

1. (Amended) An enteral composition designed for metabolically stressed patients comprising:

a protein source providing about 15% to about ~~20~~18% of the energy of the composition;

a carbohydrate source; and

a lipid source including a mixture of medium and long chair triglycerides, the enteral composition having a caloric density of at least about 1.4 kcal/ml.

3. (Amended) The enteral composition of claim 1 ~~or claim 2~~ wherein the protein source consists essentially of partially hydrolysed whey proteins.

4. (Amended) An enteral composition for a metabolically stressed patient comprising about 15% to about ~~20~~18% of the energy of the composition of partially hydrolysed whey protein

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a carbohydrate source; and

a lipid source including a mixture of medium and long chain triglycerides;

the composition having an energy density of at least about 1.4 kcal/ml and a ratio of non-protein calories per gram of nitrogen of at least about 90:1.

5. (Amended) The enteral composition of ~~any of~~ claims ~~1 to~~ 4 wherein the lipid source provides about 20% to 50% of the energy of the composition.

6. (Amended) The enteral composition of claims ~~1 to 5~~ 4 which includes at least about 100% of U.S. RDA of vitamins and minerals in about 1500 kcal.

7. (Amended) The enteral composition of ~~any of~~ claims ~~1 to 5~~ 4 wherein the composition includes per 1500 kcal of composition:

a zinc source providing from approximately 28.5 to 43.5 mg;

a vitamin C source providing from approximately 405 to 615 mg;

a selenium source providing from approximately 60 to 90 mg;

a taurine source providing from approximately 120 to 180 mg; and

a L-carnitine source providing from approximately 120 to 180 mg.

8. (Amended) The enteral composition of ~~any of~~ claims ~~1 to 7~~ 4 further including a source of β-carotene.

9. (Amended) The enteral composition of ~~any of~~ claims ~~1 to 8~~ 4 which has an energy density of about

10. (Amended) A method for providing nutrition to a metabolically stressed patient comprising the step of administering to the patient a therapeutically effective amount of a composition comprising:

a protein source comprising approximately 15% to about ~~20~~18% of the energy of the composition;

a carbohydrate source; and

a lipid source including a mixture of medium and long chain triglycerides, the enteral composition having a caloric density of at least about 1.4 kcal/ml.

Claims 11-15 have been added as follows:

11. (Newly Added) The enteral composition of claim 1 wherein the lipid source provides about 20% to 50% of the energy of the composition.

12. (Newly Added) The enteral composition of claim 1 which includes at least about 100% of U.S. RDA of vitamins and minerals in about 1500 kcal.

13. (Newly Added) The enteral composition of claim 1 wherein the composition includes per 1500 kcal of composition:

a zinc source providing from approximately 28.5 to 43.5 mg;

a vitamin C source providing from approximately 405 to 615 mg;

a selenium source providing from approximately 60 to 90 mg;

a taurine source providing from approximately 120 to 180 mg; and

a L-carnitine source providing from approximately 120 to 180 mg.

14. (Newly Added) The enteral composition of claim 1 further including a source of β-carotene.

15. (Newly Added) The enteral composition of claim 1 which has an energy density of about 1.4 to about 1.8 kcal/ml.

Please cancel claim 2 without prejudice or disclaimer.